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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,330	08/15/2001	Suresh Babubhai Chahwala	PCS10942ARTB	1670

7590 01/22/2002  
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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT PAPER NUMBER

1614

DATE MAILED: 01/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/930,330

Applicant(s)  
Chahwala et al.

Examiner  
Kevin E. Weddington

Art Unit  
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-38 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, 29 and 33 are drawn to a pharmaceutical composition comprising the NO-releasing R(+) enantiomer of amlodipine and the anti-hypertensive S(-) enantiomer of amlodipine, classified in class 514, subclass 315.
- II. Claims 21-25 are drawn to a process for the preparation of a composition with single crystals of the R(+) and the S(-) enantiomers of amlodipine, classified in class 514, subclass 315.
- III. Claim 26 is drawn to the R(+) enantiomer of amlodipine, classified in class 514, subclass 315.
- IV. Claims 27-30 are drawn to a method for manufacture of a medicament comprising the NO-releasing R(+) enantiomer of amlodipine, classified in class 514, subclass 315.
- V. Claims 31 and 32 are drawn to a method for the manufacture of a medicament comprising the R(+) and S(-) enantiomers of amlodipine, classified in class 514, subclass 315.
- VI. Claim 34 is drawn to a method of treating a condition with the S(-) and R(+) enantiomers of amlodipine, classified in class 514, subclass 315.

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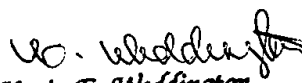
VII. Claims 35-38 are drawn to a pharmaceutical composition comprising the NO-releasing R(+) enantiomer of amlodipine and an ACE inhibitor, classified in class 514, subclasses 315 and 653.

The seven inventions are independent and distinct, each from the other as they have acquired a separate status in the art as shown by their separate subject matter for inventive effort. Further, a reference which anticipates any one of the above inventions would neither anticipate or make obvious of the other inventions. Each such invention is capable of supporting its own patent. For these reasons, the restriction requirement is proper.

To be complete, applicants' response must include a provisional election even though the requirement may be traverse.

The applicants are required to elect a single invention for examination purposes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner K. Weddington whose telephone number is (703) 308-1235.

  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington

January 18, 2002